K121008 1/1

510(k) Summary
for the Trilliant Surgical K-wires

JUN - 4 2012

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Trilliant Surgical K-wires

1. GENERAL INFORMATION

Date Prepared: March 15, 2012

Trade Name: Trilliant Surgical K-wires

Common Name: K-wires

Classification Name: Pin, Fixation Smooth

Class: II

Product Code: HTY

CFR section: 21 CFR section 888.3040

Device panel: Orthopedic

Legally Marketed Predicate Device: K-Medic External Fixation Devices - (K030336 - Teleflex Medical Group)

Submitter: Trilliant Surgical LTD
602 Sawyer Street, Suite 120
Houston, TX 77007

Contact: J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199
e-mail: jdwebb@orthomedix.net

2. DEVICE DESCRIPTION

K-wires are sharpened or blunt, smooth stainless steel pins. They come in different sizes and are used to hold bone fragments together (pin fixation) or to provide an anchor for skeletal traction. Two diameters, Ø0.045" (Ø1.143 mm) and Ø0.062" (Ø1.57 mm), of the Trilliant Surgical K-Wires are offered to accommodate various patient anatomies, injuries and/or conditions, and physician preference.

Materials:
316L Stainless Steel per ASTM F138

Function:
The K-wires are used to hold bone fragments together (pin fixation), to provide an anchor for skeletal traction and as guide pins for insertion of other implants.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The Trilliant Surgical K-wires are substantially equivalent to the predicate devices in terms of intended use, design, and materials used.

4. INTENDED USE

The Trilliant Surgical K-wires are intended for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants.

5. CLINICAL TEST SUMMARY

No clinical studies were performed

6. CONCLUSIONS NONCLINICAL AND CLINICAL

This summary concludes that Trilliant Surgical K-wires are as safe, as effective, and performs as well as the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Trilliant Surgical, LTD
% The OrthoMedix Group, Inc.
% Mr. J.D. Webb
1001 Oakwood Blvd.
Round Rock, Texas 78681

JUN - 4 2012

Re: K121008
Trade/Device Name: Trilliant Surgical K-wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: March 15, 2012
Received: April 3, 2012

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ewiel Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121008

Device Name: Trilliant Surgical K-wires

Indications for Use:

The Trilliant Surgical K-wires are intended for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121008